

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/CA2004/000666

International filing date (day/month/year)
30.04.2004

Priority date (day/month/year)
02.05.2003

International Patent Classification (IPC) or both national classification and IPC
C08B37/00

Applicant
CEAPRO INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/CA2004/000666

JC20 Rec'd PCT/PIO 25 OCT 2005

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/CA2004/000666

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-16
	No: Claims	17-22
Inventive step (IS)	Yes: Claims	1-16
	No: Claims	17-24
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/CA2004/000666

JC20 Rec'd PCT/PTO 2 5 OCT 2005

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents. If not indicated otherwise, reference is made to the passages cited in the international search report (ISR):
 - D1: WO 02/43719 A (WEISSMAN GLENN H) 6 June 2002 (2002-06-06)
 - D2: US-A-5 980 918 (KLEIN BARBARA K) 9 November 1999 (1999-11-09)
 - D3: US-A-5 518 710 (BHATTY RATTAN S) 21 May 1996 (1996-05-21)
 - D4: US-B-6 284 8861 (REDMOND MARK J) 4 September 2001 (2001-09-04)
 - D5: WESTERLUND E ET AL: "ISOLATION AND CHEMICAL CHARACTERIZATION OF WATER-SOLUBLE MIXED-LINKED B-GLUCANS AND ARABINOXYLANS IN OAT MILLING FRACTIONS" CARBOHYDRATE POLYMERS, APPLIED SCIENCE PUBLISHERS, LTD. BARKING, GB, vol. 20, no. 2, 1993, pages 115-123, XP000343989
 - D6: WIKSTROM KATARINA ET AL: "Rheological studies of water-soluble (1-3),(1-4)-beta-D-glucans from milling fractions of oat" JOURNAL OF FOOD SCIENCE, vol. 59, no. 5, 1994, pages 1077-1080, XP001194837
 - D7: WOOD P J ET AL: "LARGE-SCALE PREPARATION AND PROPERTIES OF OAT FRACTIONS ENRICHED IN (1 3(1 4)-BETA-D-GLUCAN" CEREAL CHEMISTRY, AMERICAN ASSOCIATION OF CEREAL CHEMISTS. MINNEAPOLIS, US, vol. 66, no. 2, 1989, pages 97-103, XP001194802
 - D8: US 2002/016454 A1 (HASH KIRK R ET AL) 7 February 2002 (2002-02-07)
 - D9: WO 02/02645 A (ROXDALE FOODS LTD ; GRANATE SEED LTD (NZ); MORGAN KEITH RAYMOND (NZ)) 10 January 2002 (2002-01-10)

2. **Novelty, Art. 33(2) PCT**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 17 and 18 is not new in the sense of Article 33(2) PCT.

Document D3 relates to processes of extraction of beta-glucans from barley and oat. The compositions obtained by these processes contain beta-glucan having purities of e.g 80%, 3.7 % ash, 0.5% nitrogen. Although lipid impurities are not listed as such, it is supposed from the rest of the values that they are less than 10%. ✓

The formulations disclosed in D4 also contain beta-glucan with a purity of 85%. The turbidity of the solutions is less than 11 FTU. Although it is not said which kind of impurities there are, the compositions of D4 appear to be prima facie novelty destroying for the subject-matter of claims 17 and 18. ✓

The isolation process of D5 achieves solutions with a purity of mixed-linked-beta-glucans of 96-99%. The purity of the beta-glucan obtained in D6 can also reach 99.5%. A solution of a beta-glucan of such purities would be expected to have a clarity value within the range given in claim 18.

2.2 The subject-matter of claims 19 to 22 is not new in view of documents D1 and D2. Document D1 (see example 2) discloses a composition comprising from 0.01 to 2.5 % Wt oat beta glucan and from 0.0 to 40 Wt% glycerol. Document D2 also discloses composition comprising 0.5 to 15% w/w cereal beta-D-glucan and 5-20% w/w glycerol.

2.3 The process of isolation of independent claim 1, and dependent claims 2-16 appears to be novel in the sense of Art. 33(2) PCT since none of the documents of the ISR disclose a process comprising exactly the same steps.

3. Inventive step. Art. 33(3) PCT

Documents D3, D5-D9 all disclose methods of extraction of beta-glucans from cereals.

According to the process of D3, which appears to be the closest prior art, the cereals are extracted with an alkaline solution having a pH of 8 to 12, the base-soluble beta-glucan is separated by centrifugation, dialysis or filtration, an alpha-amylase is added to eliminate contaminating starches, degraded starches are removed, and a polar alcohol (methanol, ethanol) is added to a final concentration of 20 to 90%, more preferably 40-60%, to precipitate the beta-glucans. D3 is silent about the size of particulate /insoluble material that is removed from the purified extract. The purity of the beta-glucans obtained can reach 85 %.

The problem to be solved by the present invention may be regarded as the provision of an alternative method of isolating beta(1-3)beta(1-4)glucan from cereals with high purity.

The removal of particulate/insoluble matter greater than 0.2 μm appears to allow the use of less alcohol (less than 25% w/w of an C1-C4 alcohol) in the following step of precipitating the beta-glucan. The reduction in the amount of alcohol used, apart from facilitating the manufacturing process, avoids severe dehydration of the cereal beta-glucan.

Therefore, the subject-matter of claims 1 to 16 appears to involve an inventive step in the sense of Article 33(3) PCT.